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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,431	03/06/2002	Siba K. Samal	108172-00070	2502

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EXAMINER	
HURT, SHARON L	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,431	SAMAL ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,19,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,19,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/13/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit Patent Examiner for your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Patent Examiner Sharon Hurt.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-7, 19, and 26-27) in the reply filed on October 15, 2003 is acknowledged. The traversal is on the ground(s) that there would be no undue burden to examine claims 1-25 on the merits. This is not found persuasive because the method can be used to make other products, and requires divergent search. The arguments are unconvincing and the restriction requirement is maintained. The requirement is still deemed proper and is therefore made FINAL.

Claims 8-18, and 20-25 are withdrawn from consideration as not directed to the elected claims directed to a Newcastle disease virus vaccine comprising at least two specific features.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 19 and 26-27 have been considered but are moot in view of the new ground(s) of rejection below.

On reconsideration, previous office action did not meet the burden requirement to make a proper written description rejection, 35 U.S.C. 112 first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 19 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, Newcastle disease virus Z.

The application does not contain an adequate written description of NDV Z. The specification does not mention Newcastle disease virus Z (NDV Z), nor disclose any specific characteristics of NDV Z. What is "Newcastle disease virus Z"? Is it a specific strain, or is it any strain with the features recited in the claims? Lack of description could also lead to enablement issues and deposit requirements. If a specific strain is intended, the claims are also rejected for a lack of written description of the particular characteristics of strain Z and lack of enablement of strain Z.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Millar et al., (Journal of General Virology 1988, 69, 613-620). Since the only required component in the claimed vaccine is a virus, and the reference teaches the virus. The reference teaches the same composition as the claims.

Millar teaches the nucleotide sequence of the fusion (F) and hemagglutinin-neuraminidase (HN) glycoprotein genes of extremely avirulent Newcastle disease virus (NDV) Ulster strain compared to the more virulent strains, such as Beaudette C. Millar teaches the more virulent NDV strains are suggested to be due to the open reading frame to the HN glycoprotein extending beyond the C terminus. Also, a phenylalanine residue occurs at the N terminus of the F_1 cleavage fragment in the more virulent strains. The strains that lack virulence may be due to the occurrence of a leucine residue at the N terminus of the F_1 cleavage fragment. Millar teaches the absence of paired basic amino acids at the F_0 cleavage site is common among avirulent strains of NDV, but that the N-terminal leucine on F_1 may be exclusive to the avirulent isolates. Therefore the Ulster strain virus has all of the features (1), (2) and (3), recited in claim 1.

Claims 1-3, 5 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone, H. D., (Avian Diseases Vol. 33, pages 157-162, 1989. Stone teaches a vaccine

comprising NDV strain Ulster. Since NDV strain Ulster inherently has the features (1), (2), and (3), Stone teaches the same vaccine as these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millar et al., (Journal of General Virology 1988, 69, 613-620) in view of Peeters et al., PCT WO99/66045.

Claims 4, and 6-7 differ from Millar in that Millar does not teach the specific codons recited in these claims. Millar does not teach a vaccine for NDV that carries at least one gene encoding an avian cytokine wherein said cytokine is an interleukin.

However, Peeters suggests generating infectious NDV with attenuating mutations. It would have been obvious one of ordinary skill in the art to use any convenient codons for generating the attenuating mutations taught in Millar, with reasonable expectations of success. Therefore, the invention is obvious as a whole.

Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millar et al., (Journal of General Virology 1988, 69, 613-620) and Peeters et al., PCT WO99/66045 as applied to claims 4 and 6-7 above, and further in view of Schijns et al., (Vaccine, Vol 18, pages 2147-2154, 2000). In making this rejection, applicant is denied benefit of priority to application numbers 60/132,597 and 60/171,072, because the applications do not describe the choice of a vaccine with any two mutations, out of three mutations, or a NDV carrying an avian cytokine or interleukin.

These claims differ from the above in that they require an avian cytokine, specifically an interleukin (IL), in the recombinant virus. Millar does not teach a NDV vaccine that carries at least one gene encoding an avian cytokine wherein said cytokine is an interleukin. Schijns teaches that cytokines applied as recombinant proteins or as genes do exert vaccine adjuvant activity. Schijns teaches that recombinant chicken cytokines were assessed for their potential to act as immunomodulators of vaccination-induced humoral immune response in 3-4 week old chickens. Schijns demonstrates that chicken interferon administered as recombinant protein, or by a plasmid, when given together with bacterial or viral antigen, significantly influence humoral immune responses in 3-4 week old chickens.

Peeters teaches that heterologous genes can be included in recombinant NDV. One of ordinary skill in the art would have been motivated to include a heterologous gene for chicken IL to improve immune response. Therefore, one would have reasonable expectation of success because of the fore mentioned art and it would have been obvious to make these improvements to the NDV vaccine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Housel James can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15 November 2005

James C. Housel 11/28/05

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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